Keith Altman, SBN 257309
Excolo Law PLLC
26700 Lahser Road,Suite 400
Southfield, MI 48033
516-456-5885
kaltman@lawampmmt.com
Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

SYLVESTER DUMAS, BEVERLY MATHERNE, individually, and as Executor of the Estate of ASHLEY JOSEPH MATHERNE, deceased; DONALD TINDALL; GLENDA BALLARD; RHEISSIE L. BALLARD, JR.; THOMAS MOYERS; KIMBERLY THOMPSON; and DOUGLAS THOMPSON;

Plaintiffs,

v.

JANSSEN PHARMACEUTICALS, INC., JANSSEN RESEARCH AND DEVELOPMENT, LLC; JOHNSON & JOHNSON; JANSSEN ORTHO, LLC; MITSUBISHI TANABE PHARMA HOLDINGS AMERICA, INC.; MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC.; TANABE RESEARCH LABORATORIES U.S.A., INC.; MITSUBISHI TANABE PHARMA CORP.; MCKESSON CORPORATION; and DOES 1-50;

Defendants.

Case No.: 3:16-cv-00647-L-WVG

Hon. M. James Lorenz

PLAINTIFFS' RESPONSE TO DEFENDANTS JOHNSON & JOHNSON, JANSSEN RESEARCH & DEVELOPMENT, LLC, JANSSEN ORTHO, LLC, TANABE RESEARCH LABORATORIES, U.S.A., INC., AND MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC.'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(2) AND 12(b)(6)

HEARING: July 25, 2016
CTRM: 5B

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Other Authorities

SUMMARY OF THE RESPONSE

Importantly, Defendants do **not** claim that the First Amended Complaint ("FAC"), in its present form, makes it impossible to frame an Answer or that the alleged deficiencies will hamper the Defendants' ability to conduct discovery or prepare for trial. [*See generally*, Doc. 25]. Instead, they complain only that their subjectively perceived lack of detail in the FAC's factual allegations warrants a dismissal of certain claims. [*Id.*] Put simply, the Defendants' argument is self-serving, unsupported by the rich judicial history concerning motions to dismiss, and fatally flawed.

INTRODUCTION

This product liability action arises from Defendants' design, manufacture, and marketing of the prescription drug Invokana. Invokana is a prescription drug, known as an SGLT-2 inhibitor, primarily used for the treatment of type 2 diabetes. Invokana inhibits the body's ability to absorb glucose, forcing many Invokana users into a dangerous state of ketoacidosis, a serious condition affecting the body's blood-acid concentration that can lead to hospitalization, coma, or even death.

Plaintiffs object to Defendants' motion to the extent it incorporates their previously filed motion to dismiss, Doc # 15. This is nothing but a blatant attempt to circumvent the local rules limiting motions to 25 pages. As such, to the extent that any argument relies upon such references, the Court should deny that portion of the motion.

In the event that the Court does allow such references, Plaintiff will also make references to its opposition to Defendants' motion, Doc. # 23.

The FAC was filed by Plaintiffs against Janssen Pharmaceuticals Inc. ("Janssen"), Janssen Research and Development, LLC. ("Janssen R&D"), Johnson & Johnson Co. ("J&J"), Janssen Ortho, LLC. ("Ortho"), Mitsubishi Tanabe Pharma Holdings, America, Inc.("MTH"), Tanabe Research Laboratories U.S.A., Inc. ("TRL"), Mitsubishi Tanabe Pharma Corp. ("MTPC"), Mitsubishi Tanabe Pharma Development America, Inc. ("MTPD"), McKesson Corporation ("McKesson"), and DOES 1 through 50.

This action seeks, among other relief, general and special damages and equitable relief due to Plaintiffs who suffered severe and life-threatening side effects of kidney failure and stroke, caused by the prescription drug Invokana (also known as canagliflozin). ("FAC") ¶¶1, 42 & 47).

Plaintiffs are residents and citizens of California, Louisiana, Indiana, and Virginia. (FAC ¶¶2-7). Janssen is a Pennsylvania company that is registered to do business in the United States, including the states of Pennsylvania, California, and states where Plaintiffs have resided and were treated. (FAC ¶¶11 & 12). Janssen owns Janssen R&D. (FAC ¶9). Both these companies are subsidies of J&J. (FAC ¶9). TRL is a California corporation, with a principal place of business in San Diego, California. (FAC ¶23). TRL conducted pharmaceutical research with respect to the drug Invokana and, as such, participated in the development of the drug alongside its other Tanabe

affiliates. McKesson is a corporation having its principal place of business in California. (FAC ¶25). McKesson is the nation's leading healthcare information technology company and one of the largest pharmaceutical distributors. (FAC ¶25). Defendants Janssen, Janssen R&D, and Janssen Ortho are agents or departments of Defendant J&J, and so J&J is their alter-ego. (FAC ¶65).

Plaintiffs' claims are based on product liability and Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Invokana. The claims in the FAC are brought against all Defendants, including Janssen and McKesson. This Motion to Dismiss the FAC is filed by Defendants Janssen and McKesson alleging lack of personal jurisdiction and lack of plausible claim. Defendants also claim that Plaintiffs' design defect-based claims are preempted by federal law.

Contrary to Defendants' assertions, Mitsubishi Tanabe Pharma Corp. ("MTPC") was served on April 13, 2016. Mitsubishi Tanabe Holdings America was served on April 15, 2016. Plaintiffs are preparing a default motion against both of these parties.

STATEMENT OF THE CASE

Plaintiffs were prescribed Invokana which had severe and life-threatening side effects, including kidney failure. (FAC ¶¶42-47, 94-99). The drug is currently approved only for improvement of glycemic control in adults with type 2 diabetes. (FAC ¶53).

Defendants MTPC, MTH, MTPD, and TRL designed, developed, and marketed Invokana with the other Defendants. (FAC ¶67). Janssen acquired the rights to Invokana in North America, and marketed, advertised, distributed, and sold the drug in the United States, including California. (FAC ¶¶ 12 & 71). Janssen R&D submitted the New Drug Application to the FDA for approval to market Invokana in the U.S. (FAC ¶72).

The FDA approved Invokana for the treatment of type 2 diabetes. (FAC ¶73). Once approved, Defendants aggressively marketed Invokana to doctors and directly to patients. (FAC ¶75). Defendants' marketing overstated Invokana's benefits while understating its risks, thus failing to adequately warn physicians and patients about diabetic ketoacidosis, kidney failure, stroke and cardiovascular injury. (FAC ¶¶ 76-77).

Defendants. Individually and in concert, knew the risks of diabetic ketoacidosis, kidney failure, and other serious complications related to Invokana, but they misrepresented that the drug is safe and effective in treatment for type 2 diabetes mellitus. (FAC ¶¶ 83 & 84). Defendants failed to adequately warn consumers and physicians about the risks associated with Invokana. (FAC ¶90). Several safer alternatives were available to treating diabetes, including diet and exercise and other antidiabetic agents. (FAC ¶93).

In 2015 the FDA announced that SGLT2 inhibitors may lead to diabetic ketoacidosis and that Invokana causes premature bone loss and fractures. (FAC ¶¶ 106 & 107). On October 16, 2015, Health Canada, the Canadian drug regulatory authority,

announced that Invokana can cause acute kidney injury. (FAC ¶108). On December 4, 2015, the FDA announced a label change for SGLT2 to include a warning of ketoacidosis and the risk of too much acid in the blood. (FAC ¶109). Prior to the FDA's December 4, 2015, announcement, Invokana's label failed to warn consumers of the serious risk of developing diabetic ketoacidosis. (FAC ¶110). Its current label does not warn of the serious risks of developing bone fractures and kidney injury. (FAC ¶111).

Despite the FDA's announcements, Defendants continued to engage in aggressive direct-to-consumer and physician marketing for Invokana. (FAC ¶112). Plaintiffs have endured pain and suffering, emotional distress, loss of enjoyment of life, loss of life and economic loss, including significant expenses for medical care and treatment which will continue in the future. (FAC ¶100). Plaintiffs seek actual, compensatory, and punitive damages from Defendants.

STANDARD OF REVIEW

"A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (citing *Bell Atlantic Corp.*, 550 U.S. at 556). "[D]etermining whether a complaint states a plausible claim is context-specific," and the court should "draw on its experience and common sense" in making the ultimate determination. *Id.* at 663-64 (citing *Bell Atlantic Corp.* 550 U.S.at 556).

ARGUMENT

I. Defendants Selective, Out of Context Citations of the FAC is Misleading to the Court

Consistently throughout their brief, Defendants claim that Plaintiffs' FAC is devoid of particularity and conclusory in nature. To further this, Defendants selectively cite passages from the FAC taken out of context and without other paragraphs that collectively establish that Plaintiffs have pled in a non-conclusory manner and with the required level of specificity.

For example, Defendants suggest that *Fleming v. Janssen Pharms., Inc.*, 2016 WL 3180299 (W.D. Tenn. June 6, 2016) stands for the proposition that Plaintiffs design defect claims and negligent design claims should be dismissed. In support of Defendants premise, Defendants cite a single paragraph of the FAC claiming that this is "virtually identical" to the claims in *Fleming*. Perhaps Defendants mixed up the Fleming complaint with the FAC because it is clear that Plaintiffs have said far more about the design defect that the one paragraph, FAC ¶49. See. FAC ¶¶ 49-52, 84-87, and 126-131. In fairness, Defendants should have shown how the above paragraphs collectively were addressed by the *Fleming* Court and not just cited to one individual paragraph.

There are many other examples of the same behavior. If Defendants intend to show the Court that Plaintiffs have failed to meet some pleading standard, then Defendants should provide a complete citation. By only citing to one of many

paragraphs, Defendants attempt to mislead this Court. This should not be allowed and Defendants' motion should be denied.

II. Defendants reliance on Fleming and Brazil is Misplaced.

Defendants tout *Fleming* and *Brazil v. Janssen Research & Dev. LLC,* No. 4:15-CV-0204-HLM (Mar. 24, 2016) as support for their motion to dismiss. Nowhere, though, do Defendants show how Plaintiffs have made only conclusory statements as was apparently so in *Fleming* and *Brazil*. In fact, as discussed below, Plaintiffs very much plead with particularity that may be absent from *Fleming* and *Brazil*. Defendant should not be simply able to suggest to this Court should apply these opinions without establishing that the pleading defects in those cases exist in this case.

Furthermore, *Fleming* and *Brazil* involved questions of state law, Tennessee and Georgia respectively. As such, the application to the instant case is spurious at best and this Court should rely upon out of district opinions with caution, particularly when they apply law other than that of the Forum state.

III. All Defendants Have a Connection to California and Are Subject to Personal Jurisdiction

Defendants' argue that specific jurisdiction is lacking over the non-California defendants because the non-California defendants did not direct their activities towards California. Not so. In fact, Plaintiffs have very specifically pled that the non-California Defendants' conduct in concert with the California defendants has led to Plaintiffs injuries. Defendants TRL and McKesson are California entities. (FAC ¶¶ 23-26). Thus,

each Plaintiff has a nexus to California. Furthermore, Plaintiffs allege that the Defendants acted in concert with the California Defendants. (FAC ¶¶ 30, 66, 67, 83, 102, 105, and 185).

In addition, throughout the complaint, Plaintiffs have alleged that Defendants' conduct has a sufficient California nexus such that specific jurisdiction over each Defendant is appropriate. Specifically, Plaintiffs have alleged in the FAC:

> 28. All Defendants are authorized to do business in California and derive substantial income from doing business in this state.
>
> 37. At all times relevant to this action, Defendants were engaged in substantial business activities in California, including disseminating inaccurate, false, and misleading information about INVOKANA to health care professionals in California, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout California and throughout the United States.
>
> 39. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including INVOKANA, within California with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.
>
> 57. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities at residents of California.
>
> 58. The INVOKANA-related pages on the Defendants' web sites are accessible from within California, and have been indexed by search engines so that they are located through searches that are conducted from within California.
>
> 272. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars in ill-gotten gains from the sale and prescription of INVOKANA® in California, sold in large part as a result of the acts and omissions described herein.

Thus, the complaint is clear that this is not a case of casual contact with California. Defendants, acting in concert, systematically directed their activities at California. "Hundreds of millions of dollars" were derived from Invokana sales in California. Furthermore, as discussed above, two of the defendants are California corporations.

Nowhere do Defendants argue that any Plaintiff claim against TRL and McKesson should be dismissed for lack of personal jurisdiction. Because Plaintiffs have alleged that the non-California Defendants acted in concert with the California Defendants, each Plaintiff has a California based claim against each Defendant. By acting in concert with California Defendants, the non-California Defendants have reasonable availed themselves of specific jurisdiction. Therefore, the Court has personal jurisdiction over all Defendants.

IV. Plaintiffs Have Alleged with Particularity the Involvement of Each Defendant

Defendants completely ignore numerous sections in Plaintiffs complaint which set forth how each Defendant was involved with Invokana. Any reliance on *Brazil* is misplaced because the *Brazil* plaintiffs did not provide such detail as here.

With respect to J&J, Plaintiffs have pled with particularity that J&J oversaw the promotion of Invokana (FAC ¶60) and could have provided additional warnings (FAC ¶62). Furthermore, Plaintiffs have alleged that J&J exercised control over Janssen, JRD, and Ortho and that the control so substantially dominates these entities that J&J is the

alter ego if Janssen, JRD, and Ortho. Plaintiffs also identify the role and interaction of the remaining defendants in the FAC:

> 63. Defendant J&J so substantially dominates and controls the operations of JANSSEN, JANSSEN R&D, and JANSSEN ORTHO, that it could have required them to make changes to the safety label of the drug INVOKANA.
>
> 64. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of INVOKANA and direct these activities on behalf of J&J, JANSSEN, JANSSEN R&D, and JANSSEN ORTHO.
>
> 65. In fact, J&J so substantially dominates and controls the operations of JANSSEN, JANSSEN R&D, and JANSSEN ORTHO, that the entities are indistinct for purposes of this litigation such that JANSSEN, JANSSEN R&D, and JANSSEN ORTHO should be considered agents or departments of J&J, and J&J is their alter-ego.
>
> 66. Employees of TANABE, TANABE HOLDINGS, TANABE RESEARCH, and TANABE DEVELOPMENT hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of INVOKANA and direct these activities on behalf of J&J, JANSSEN, JANSSEN R&D, and JANSSEN ORTHO.
>
> 67. On information and belief, Defendants TANABE, TANABE HOLDINGS, TANABE DEVELOPMENT, and TANABE RESEARCH, in collaboration with the other Defendants, designed developed, and marketed the diabetes drug, INVOKANA in the United States, and has made misrepresentations regarding the safety of the drug.

Thus, Plaintiffs have clearly identified that each Defendant was directly involved with Invokana, and as discussed above, that all Defendants acted in concert. This Court has personal jurisdiction over all Defendants and Defendants' motion should be denied.

V. The Court Has Personal Jurisdiction over the Non-California Plaintiffs' Claims against Non-California Defendants Because They Have a California Nexus

Defendants wrongly claim that Plaintiffs' claims are not properly joined. (ECF # 15, p.6). Joinder of claims has been found proper "where plaintiffs whose causes of action are based upon misrepresentation, or conspiracy and fraud allege a single scheme, depending on the same basic misrepresentations and leading to a series of transactions exactly similar in kind and manner of operation." *Anaya v. Superior Court*, 160 Cal. App. 3d 228, 232, (Ct. App. 1984). In the instant case, Plaintiffs' claims arise out of the same transaction and occurrence. Specifically, Plaintiffs' claims arise out the use of the prescription drug Invokana. Plaintiffs and their physicians or healthcare providers relied on Defendants' claim that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. (FAC ¶118). Here Plaintiffs' causes of action are based upon Defendants' single scheme of developing, marketing, advertising and selling the drug which led to a series of substantially similar transactions. Therefore, joinder of claims is proper.

As such, there is a California nexus between Defendants' conduct in California and Plaintiffs' injuries, irrespective of Plaintiffs' domicile. Given this connection, it is clear that California has jurisdiction over all Defendants for all Plaintiffs' claims.

Defendants' argument for lack of specific jurisdiction for the claims of the non-California plaintiffs is the assertion that none of the non-California Defendants with respect to the non-California plaintiffs has a California connection. As discussed above, there is a clear California connection between the non-California plaintiffs and the non-

California defendants via California Defendants TRL and McKesson. Therefore, the Court has personal jurisdiction over all Defendants claims with respect to all Plaintiffs

VI. Plaintiffs Have Stated Plausible Claims for Relief against Ortho

Defendants claim that Plaintiffs make no allegations specifically against Ortho. Aside from the concerted action allegations discussed above, Defendants surely overlooked ¶ 68 of the FAC:

> On information and belief, Defendant JANSSEN ORTHO failed to properly manufacture INVOKANA to ensure consistent quality with each batch that matched the (flawed) design specifications. The failure of consistent manufacture stemmed from faulty manufacturing processes, sub-par raw materials, and failure to properly clean and maintain equipment and other manufacturing facilities to ensure no cross-contamination from microbes and cleaning products.

Therefore, Plaintiffs have made specific allegations Ortho and Defendant's motion should be denied.

VII. Defendants' Fail to Show Why there is no Personal Jurisdiction over MTPD

Defendants' arguments are fantastic as they concede that Plaintiffs have made allegations of the involvement of MTPD[2]. Nevertheless, according to Defendants' own self-serving statements, MTPD had nothing to do with Invokana. Thus, Defendants look to the Court to take Defendants' statements as true- the exact opposite of what the Court is required to do when evaluating a motion to dismiss.

[2] Doc 25-1, Section A.2.c., p12.

Furthermore, as discussed above, Plaintiffs have alleged with particularity that MTPD acted in concert with the other defendants concerning Invokana. This concerted conduct has a California nexus as also shown above. Therefore, Plaintiffs allegations are sufficient to establish personal jurisdiction over MTPD. Defendants' motion should be denied.

VIII. Plaintiffs Have Adequately Pled Failure to Warn Claims Against Defendants

As stated by Defendants, Plaintiffs have met the pleading standard for a failure to warn claim. (ECF #15, p. 12). First, Plaintiffs have pled that Defendants have failed to warn both physicians and patients. (FAC ¶¶ 56, 62, 77, 83, 89, 90, 116, 140-156). Plaintiffs have also pled that the failure to warn led doctors and patients to use Invokana and did not properly instruct doctors and patients how to manage the risks associated with the use of Invokana. (FAC ¶¶ 117, 154). The use of Invokana led to Plaintiffs' injuries. (FAC ¶¶42 – 47).

The Invokana label is not adequate with respect to Plaintiffs' injuries. Defendants argue as if the mere fact that an adverse event is described somewhere in the label inoculates Defendants from liability. In other words, Defendants would have this Court believe that adequate labeling is a simple binary state- if the event is somehow mentioned somewhere on the label, then the label must be adequate. This is completely wrong and the U.S. Supreme Court has said as much: "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of

its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570-571 (2009). Thus, a label that might be adequate one day may become inadequate the next- the exact situation of Invokana.

There are multiple sections of a label that have varied levels of importance concerning warnings. Furthermore, placement on a label is also a reflection of the degree of evidence of a relationship between a drug and an adverse event. With respect to "renal failure", Defendants are correct that the term does occur in the label in the "adverse events" section, the least important section of the label, which "must describe the overall adverse reaction profile of the drug based on the entire safety database." (21 C.F.R. § 201.57(c)(7)). Contrast this with the "warnings and precautions" section of the label which:

> [M]ust describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification). (21 C.F.R. § 201.57(c)(6)).

While everything in the warnings and precautions section also qualifies as an adverse event, the converse is not true. An event listed in the warnings and precautions section of the label garners far more attention by doctors because of its implications.

Defendants completely misrepresent to this Court that the label warns of the ***risk*** of renal failure. It most certainly does not. The label does nothing more than state in the adverse event section that there is an increased ***incidence*** of renal failure in those taking Invokana. That is not the same. For example, when there is an increased risk, the label specifically says so as in section 5.5 where it states: "INVOKANA increases the risk of genital mycotic infections."

As to warnings to the patient, Defendants conveniently ignore the existence of a medication guide for Invokana which required warnings to be provided directly to Plaintiffs. (FAC ¶ 114). Here, Defendants were required by the FDA under 21 C.F.R § 208 to issue a medication guide, after it was determined that Invokana posed a serious and significant public health concern, requiring the distribution of FDA-approved patient information. This medication guide is required to provide information ***specifically and directly*** to the patient independent of the physician and was expected to be delivered to, read, and understood ***by the patient***. Medication Guides are not required for all drugs and are only used when the FDA makes its specific determination that one is needed. Under these special circumstances, a duty to the patient was imposed on Defendants under 21 C.F.R § 208, and Defendants failed to satisfy this duty in the same was as physicians. As such, the learned intermediary doctrine does not bar Plaintiffs' claims.

Defendants attempt to hide behind learned intermediary, but then seek to disavow that the physician must weigh the risks and benefits in prescribing the drug. A learned intermediary is expected to weigh ***all*** of the labeled risks and the benefits of a drug before prescribing the drug. If Defendants failed to provide adequate information on the risks as they did here, then physicians are not the learned intermediary Defendants would have the Court believe them to be. Plaintiffs have specifically pled that physicians would have acted differently if aware of Invokana's true risks. (FAC ¶ 117). Thus, Defendants' arguments that failure to warn claims should be dismissed if the patient's event is different than an inadequately warned event fail.

Therefore, Plaintiffs have adequately stated a cause of action for failure to warn and because the adequacy of the label is a question of fact, the label cannot be found to be adequate as a matter of law. As such, Defendants' motion should be denied.

IX. Plaintiffs Have Pled Adequate Facts to Support Claims against All Defendants

Once again, this Court should deny Defendants' motion because of the improper reference to other briefing to circumvent the Court's limits on pages. In the event that the Court does entertain Defendants' motion in this regard, Plaintiffs respectfully refer the Court to Plaintiffs' response, Doc. 23, Sections III-VII VIII, p. 9-21.

Using just one example from Plaintiffs Doc. 23, Defendants' claimed that negligence, gross negligence, and negligent misrepresentation are insufficiently pled.

(ECF # 15, p. 13). However, the complaint has sufficiently alleged negligence specifying the particular negligent conduct of Defendants.

As to negligence, "it is sufficient to allege that an act was negligently done by defendant and that it caused damage to plaintiff." *Rannard v. Lockheed Aircraft Corp.*, 26 Cal. 2d 149, 154, (1945). "[I]t is sufficient to allege the negligence in general terms, specifying, however, the particular act alleged to have been negligently done." *Id.*

Plaintiffs' FAC includes allegations of duties owed to Plaintiffs by Defendants[3]. Plaintiffs allege that Defendants breached these duties[4]. Defendants' breaches caused Plaintiffs' injuries[5]. Thus, Plaintiffs have pled the necessary elements for negligence, gross negligence, and negligent misrepresentation. Despite Defendants protestations, Plaintiffs have pled these elements with sufficient particularity to enable Defendants to adequately respond to the complaint.

Defendants arguments for dismissal are premised on the belief that Plaintiffs' negligence claims are solely related to design defect and warnings claims. They then claim that since the design defect claims and warning claims must be dismissed, so too must the negligence claims. As shown above, Plaintiffs' design defect and failure to warn claims are viable. Therefore, Defendants arguments fail on their face.

X. Plaintiffs Have Adequately Stated Claims Against TRL

[3] FAC ¶¶ 62, 116, 152, 159, 161-163, 165, 166, 179, 219, 221, 234, 239, 284.
[4] FAC ¶¶ 166, 174, 180, 219, 285
[5] FAC ¶¶ 117, 176, 184, 229

a. TRL is not immunized from liability

Defendants try to bamboozle this Court proclaiming that there is no liability against TRL because there can be no liability against a clinical researcher. In furtherance of this goal, Defendants cite numerous cases concerning the same clinical researcher, most of which has little, if any analysis.

Defendants rely upon *Sink v. Warner-Lambert*, No. CV-02-9570, 2003 U.S. Dist. LEXIS 27874, at *24 (C.D. Cal. 2003). This opinion has no precedential value as the total extent of the opinion is:

> The Court, having considered the motions and other documents in support of and in opposition to the motions, including the supplemental [26] briefing requested from the parties, having heard the arguments of counsel, and being fully advised in the matter, finds that Dr. Jerrold Olefsky ("Dr. Olefsky") owed no legal duty to any of the plaintiffs, and, therefore, there is no possibility that the plaintiffs can prove a cause of action against Dr. Olefsky. Thus, Dr. Olefsky must be disregarded for purposes of determining federal diversity jurisdiction. Accordingly, this Court has diversity jurisdiction over each of these actions.
>
> *Julia Sink v. Warner-Lambert Co.*, 2003 U.S. Dist. LEXIS 27874, *25-26 (C.D. Cal. Feb. 19, 2003)

There is no discussion of the Court's reasoning, no discussion of any precedent, and further no explanation as to whether the Court's ruling is in general as a matter of law, or based upon the specifics of this case.

Defendants fare no better with *Skinner v. Warner-Lambert Co.*, No. CV 03-1643, 2003 WL 25598915 (C.D. Cal. Apr. 28, 2003). This opinion, written by the same judge as *Sink* concerning the same Defendant is also devoid of any discussion. Because there

is no discussion in either *Sink* or *Skinner*, these opinions offer no help to Defendants. Furthermore, as discussed below, Plaintiffs have pled multiple causes of action against TRL. Plaintiffs adequately pled viable causes of action under California law against a legitimate local defendant, TRL, which was integrally involved in ***at least*** the development of Invokana. The same could be said for the other authority cited by Defendants.

Furthermore, these cases are not instructive because although TRL is alleged to have been involved in research associated with Invokana, TRL is not an independent clinical researcher that is implicated in the cases cited by Defendants. Here, TRL is a subsidiary of Mitsubishi Tanabe Pharma Corporation, another defendant in the instant case. To suggest that this is the same arrangement as the clinical researchers in Defendants' cited cases is simply fantastic. Defendants do not cite to a single case where a defendant-subsidiary of another defendant is immunized where the subsidiary-defendant is alleged to have engaged in research on the product subject to the action. As such, the cases cited by Defendants are irrelevant to TRL's liability.

Astonishingly, Defendants cite to *McCall v. Genentech, Inc.*, No. 3:10-CV-1747-B, 2011 WL 2312283, at *4 (N.D. Tex. June 9, 2011) as support for the no liability on clinical researchers. A reading of this case shows that the court clearly distinguished between companies involved in the research and development of the product, as with TRL, and independent clinical researchers. In *McCall*, the court only dismissed claims

against the independent clinical researchers. Therefore, Defendants use of McCall is completely irrelevant and misleading because TRL is not an independent clinical researcher.

Simply put, there is no immunity for defendants who perform pharmaceutical research and are a subsidiary of another defendant. Thus, Defendants arguments that TRL is immunized fail.

b. TRL's untested self-serving declaration by its president does not establish the lack of involvement of TRL with Invokana

In a desperate attempt to keep this case from being remanded to California state court where it belongs, Defendants introduce an untested self-serving declaration from the president and chief executive officer of TRL. (ECF # 1, Ex B, "the Declaration"). While there is some support that the Court can look beyond the pleadings when considering a motion to remand, the Court must still take Plaintiffs pleadings as true. In the Declaration, TRL states that it had nothing to do with Invokana. As Defendants would have it, this Court should simply dismiss Plaintiffs complaint with respect to TRL based upon TRL's self-serving statements. If only litigation were that simple. With that context, the Declaration is in conflict with Plaintiffs' complaint and should not be accepted without Plaintiffs having an opportunity to test its veracity and completeness.

Defendants proclaim that Plaintiffs were fully aware that TRL had nothing to do with Invokana because of the Declaration. This is untrue. First, Plaintiffs have no obligation to accept an untested self-serving declaration of an officer of a defendant.

Second, even on its face, there is the possibility that TRL may have had something to do with Invokana. At ¶ 6, the Declaration discusses changes made in TRL in 2010. The first submission to the FDA for Invokana was on May 25, 2007[6]. Therefore, for at least three years before TRL's reorganization, Invokana had been in development. In all likelihood, Invokana was in development for much longer. Thus, the activities within TRL for several years before its reorganization are in question.

At ¶ 7, the Declaration mentions that Invokana was approved in 2013 in an attempt to mislead the reader to believe that because TRL claims it did not work on Invokana since 2010, the 2013 date means it had nothing to do with Invokana. These concerns demonstrate why this Court should not accept the Declaration at all since it is contested by the plain language of the complaint at ¶ 24: "TANABE RESEARCH conducts pharmaceutical research, including with respect to INVOKANA." If this Court chooses to entertain the Declaration, Plaintiffs' allegations create a question of fact and discovery should be allowed concerning the contents. In that event, though, the Court must deny the motion to dismiss against TRL, because it is possible to recover against TRL.

Defendants further aver that Plaintiffs have not specified what role TRL played with respect to Plaintiffs claims. Again, Defendants simply ignore Plaintiffs' complaint. *See* FAC ¶¶ 66-67, 201, 213, and 247. By ignoring or failing to explain how these

[6] Plaintiffs request the Court to take judicial notice of the FDA Summary Review for Invokana on page 2 of the document located at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000SumR.pdf.

paragraphs do not allege plausible claims, Defendants again seek to mislead this Court. There is no question that TRL's involvement is well pled despite Defendants' unsupported claims that Plaintiffs must do more.

Thus, without getting assessing the appropriateness of the Declaration, Plaintiffs have stated causes of action against TRL. At most, the Declaration creates a question of fact which must be resolved in favor of Plaintiffs. In the event that this Court finds that the Declaration is persuasive, and it should not for the reasons above, Plaintiffs should be allowed discovery prior to the Court ruling on the instant motion.

XI. None of Plaintiffs' Claims Are Preempted by Federal Law

This Court should deny Defendants' motion with respect to preemption on its face because Defendants have improperly referenced briefing in another document to circumvent the local rules on the length of briefs. In the event that the Court concludes that this is proper, Plaintiffs reference their briefing on preemption in Doc. 23, Section VIII, p. 21-28 on Preemption. Plaintiffs arguments are the same as to why none of Defendants' claims are preempted.

Furthermore, Defendants motion states: "Plaintiffs' Claims Against Johnson & Johnson, Ortho, MTPD, And TRL Are Preempted By Federal Law.[7]" Defendants essentially maintain that all Plaintiff's claims against these Defendants should be dismissed due to preemption without specifying which claims should be dismissed and

[7] Doc. 25-1, Sec. III.F.

why they should be dismissed. It appears that Defendants adopt a double standard when the argue that Plaintiffs' motion should be dismissed because of failure to plead with particularity while at the same time making arguments that are so unclear as to defy all reasonable attempts to comprehend. As such, Plaintiffs cannot fairly respond to Defendants' motion in this regard and Defendants motion should be denied.

Since Plaintiffs' original briefing, the court in *Fleming* ruled that the design defect claims were preempted because of *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281 (6th Cir. 2015). Most important, though, is that the *Fleming* Court felt compelled to follow *Yates* because it was binding authority in the circuit. Nevertheless, as discussed in Doc. 23, Section VIII, p. 21-28 on Preemption, *Yates* can be distinguished because (1) it was decided at the motion for summary judgement stage and (2) it found that in that particular case, plaintiffs had failed to show how defendants could have designed a different drug prior to approval. As such, *Yates* is not binding and is easily distinguished.

Alternately, should this Court find Plaintiffs' FAC defective in any way, Plaintiff respectfully requests leave to amend. Under Rule 15(a)(2), leave to amend should be "freely" granted when "justice so requires."

Additionally, to the extent this Court chooses to entertain the jurisdictional or preemption argument proposed by Defendants, Plaintiff respectfully requests leave to conduct discovery. "A district court has discretion whether to hold in abeyance a

decision on a motion to dismiss for lack of personal jurisdiction to enable the party to conduct discovery." 5A *Federal Prac. & Proc.* § 1351. And while Plaintiff disputes the legal rationale of *Yates*, 2015 U.S. App. LEXIS 21428, Defendants' own authority recognizes that the potential application of the preemption doctrine to brand name drug manufacturers turns on the facts, which therefore necessitates discovery. *Id.* at *32–33. If the Court finds Plaintiff has not sufficiently established that Janssen targeted California for jurisdictional purposes, Plaintiff should be able to take discovery to develop facts that relate to: Janssen's contacts with California; its targeting of markets in California; its involvement in the development, marketing and sale of Invokana; its agreements with J&J, Mitsubishi Tanabe, McKesson, and related companies regarding Invokana; and Defendants' corporate structure. This discovery is warranted because the details of the processes and agreements by which Invokana came to California is not known at this time. Discovery is necessary for Plaintiff to determine what role Janssen played in the development of Invokana, and the extent to which its role included contacts with California. In addition, discovery is necessary to uncover who would carry out which tasks with respect to designing, developing, testing, marketing, selling, and earning profits from the sale of Invokana.

Further, should the Court decide to entertain Defendants' faulty preemption argument, Plaintiff must first be able to take discovery into the science underlying Invokana itself — its design, development, and production — how it works, and how

(or if) it can be made safer. Only limited information about the design, development, testing, and production of Invokana are publicly available. If permitted to conduct discovery, Plaintiff would seek, at a minimum, Corporate Representative depositions pursuant to F.R.C.P. 30(b)(6) and related document requests on the following topics: (1) J&J and Janssen's corporate structure; (2) their involvement in the development, manufacturing, sale, and promotion of Invokana; (3) contractual agreements among the Defendants; (4) studies and other clinical trials related to Invokana; (5) the design, development, and testing of Invokana; and (6) scientific studies showing increased risks of Invokana and related communications with the FDA.

CONCLUSION

WHEREFORE, for the reasons discussed, Plaintiffs respectfully request this Honorable Court DENY Defendants' Motion to Dismiss the FAC in its entirety.

DATED: July 11, 2016.

Respectfully submitted,

By: s/ Keith Altman

Keith Altman, SBN 257309
Excolo Law PLLC
26700 Lahser Road,Suite 400
Southfield, MI 48033
516-456-5885
kaltman@lawampmmt.com
Attorneys for Plaintiffs